## UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

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UNITED STATES OF AMERICA ex rel.	)	
BANIGAN & TEMPLIN, et al.,	)	
	)	
Plaintiffs,	)	
	)	Civil No. 07-12153-RWZ
-against-	)	
	)	
ORGANON USA INC., OMNICARE,	)	
INC., and PHARMERICA, INC.,	)	
	)	
Defendants.	)	
	X	

# UNITED STATES' STATEMENT OF INTEREST IN RESPONSE TO DEFENDANT OMNICARE, INC.'S MOTION TO RECONSIDER

The United States of America, as the real party-plaintiff in interest in this action, submits this Statement of Interest pursuant to 28 U.S.C. § 517, to respond to certain arguments made by defendant Omnicare, Inc. (Omnicare), in its motion to reconsider or, in the alternative, certify for interlocutory appeal the Court's June 1, 2012 order. The United States remains the real party in interest in this matter, even where it has not intervened in the action. *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 231 (1st Cir. 2004). In addition, because the False Claims Act (FCA), 31 U.S.C. §§ 3729-3733, is the United States' primary tool used to prosecute fraud on the government, the government has a substantial interest in the development of the law in this area and in the correct application of that law in this, and similar, cases.

The United States submits this brief to make two principal points. First, any analysis of whether a particular relator's complaint is barred by the FCA's "first to file" rule must focus solely on the text of the complaints themselves, and not on any subsequent investigation by the United States of such complaints. Second, the 1986 amendments to the FCA specifically eliminated the

government knowledge bar to *qui tam* filings, and there is no basis in the FCA to bar suits based solely on the government's alleged awareness of underlying fraud.

#### **BACKGROUND**

Relators, James Banigan and Richard Templin, filed this action under the *qui tam* provisions of the FCA, 31 U.S.C. § 3730, which permits private parties to file an action on behalf of the United States. Under the FCA, a proper relator is entitled to share in the proceeds of the prosecution of the claims in his complaint, with the United States retaining, at a minimum, seventy percent of the proceeds of the action. The FCA requires that the relator file the action under seal, during which time the United States may evaluate the allegations and investigate the claims in the complaint so that it may decide whether to intervene in and take over the action. 31 U.S.C. § 3730(b)(2).

On April 19, 2010, and September 7, 2010, respectively, the United States notified the Court that it was declining to intervene with respect to the claims raised by Relator in this action. On June 2, 2012, the Court dismissed a number of claims in Relators' Third Amended Complaint with respect to defendants Organon USA Inc. (and related entities) and Pharmerica Long-Term Care, LLC. The Court relied in part on 31 U.S.C. § 3730(b)(5), which provides that once a relator has filed a *qui tam* suit under the FCA, "no person other than the Government may intervene or bring a related action based on the facts underlying the pending action." 31 U.S.C. § 3730(b)(5). The Court declined to dismiss related claims against defendant Omnicare.

In its motion to reconsider, Omnicare effectively argues that, in evaluating the first to file issue, the Court should go beyond the text of the earlier-filed *qui tam* complaints and consider the scope of the investigation undertaken by the United States in response to prior complaints.

Omnicare Memorandum at 12-13. As set forth below, there is no basis under the FCA for

undertaking such an inquiry, and the first to file issue must be decided only upon a comparison of the allegations pled in relators' complaints.

#### <u>ARGUMENT</u>

### I. THE FIRST TO FILE ANALYSIS MUST BE BASED UPON THE TEXT OF RELATORS' COMPLAINTS.

In *United States ex rel. Duxbury v. Ortho Biotech Products, L.P.*, 579 F.3d 13 (1st Cir. 2009), the First Circuit held that first to file disputes under the FCA must be evaluated based on a careful consideration of the allegations in the relators' complaints. *See id.* at 32. "All courts that have addressed the issue have interpreted § 3730(b)(5) to bar 'a later allegation [if it] states all the *essential facts* of a previously-filed claim' or 'the same *elements* of a fraud described in an earlier suit." *Id.* at 32 (quoting *United States ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 232-33 (3d Cir. 1998)). The First Circuit rejected an "identical facts" test, finding that a complaint need not be identical to a prior complaint to be barred by 31 U.S.C. § 3730(b)(5). *Duxbury*, 579 F.3d at 32.

In evaluating the relators' complaints presented in *Duxbury*, the First Circuit carefully compared the specific allegations and determined that relator Duxbury's original complaint did not allege the fraud scheme set forth in the second relator's complaint. In addition, when asked to consider information provided by relator Duxbury outside of the complaint, the First Circuit declined to do so, holding that "[t]he 'first to file' rule is 'exception-free.'" *Duxbury*, 579 F.3d at 33 (quoting *United States ex rel. Lujan v. Hughes Aircraft Co.*, 243 F.3d 1181, 1187 (9th Cir. 2001)); *see also United States ex rel. Nowak v. Medtronic, Inc.*, 806 F. Supp. 2d. 310, 334 (D. Mass. 2011) (only complaints are compared in determining first to file). The court held that the allegations had to be included in the relator's complaint in order to be considered under the first to file analysis.

Under *Duxbury*, therefore, there is no basis for this Court to consider the scope of the government's investigation of Omnicare or of any subpoena response by Omnicare in determining any first to file issue involving relators' complaints here. These matters are extraneous to the analysis - which must focus solely on the allegations pled in relators' complaints.

### II. THE 1986 AMENDMENTS TO THE FCA SPECIFICALLY ELIMINATED THE GOVERNMENT KNOWLEDGE BAR.

In arguing that its subpoena response should somehow be used as a basis to bar relators' claims here, Omnicare appears to be attempting to revive the government knowledge bar to *qui tam* complaints. The 1986 amendments to the FCA, however, specifically put to rest the argument that prior government knowledge of fraud can somehow bar a suit under the FCA. As the First Circuit noted in *Duxbury*, the 1986 amendments abolished "the 'government knowledge' regime entailed by the 1943 jurisdictional bar, which Congress concluded 'proved too restrictive of *qui tam* actions, resulting in the under-enforcement of the FCA." *Duxbury*, 579 F.3d at 26 (quoting *United States ex rel. Rost v. Pfizer, Inc.*, 507 F.3d 720, 729 (1st Cir. 2007)). In so doing, "Congress thus changed the focus of the jurisdictional bar from evidence of fraud inside the government's overcrowded file cabinets to fraud already exposed in the public domain." *Duxbury*, 579 F.3d at 26 (quoting *United States ex rel. Findley v. FRP-Boron Employees' Club*, 105 F.3d 675, 684 (D.C. Cir. 1997)).

Here, Omnicare effectively argues that the Court should consider whether, among the millions of pages it produced to the government, there were documents relevant to the relators' allegations regarding Remeron. This is exactly the type of inquiry that the 1986 amendments foreclosed, as the First Circuit explained in *Duxbury*. Based on the FCA and the above case law, the United States respectfully asks this Court to reject Omnicare's argument.

Dated: August 3, 2012 Respectfully submitted,

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### **CERTIFICATE OF SERVICE**

I hereby certify that the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants.

Dated: Boston, Massachusetts August 3, 2012

> By: /s/Zachary A. Cunha ZACHARY A. CUNHA Assistant U.S. Attorney